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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,822	02/08/2002	Gregory E. Hardee	ISIS-4947	4141

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EXAMINER	
GIBBS, TERRA C	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,822	HARDEE ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-25 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to the Election filed October 1, 2003.

Claims 1-28 are pending in the instant application.

Claims 1-25 and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on October 1, 2003.

Claims 26 and 27 have been examined on the merits.

Election/Restrictions

Applicant's election with traverse of Group II (claims 26 and 27), filed October 1, 2003 is acknowledged.

Priority

The reference to priority to USSN 09/256,515, filed February 23, 1999, in the first line of the Specification is acknowledged.

Information Disclosure Statement

The information disclosure statement filed May 22, 2002 is acknowledged. The references referred to therein have been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Dean et al. [WO 98/49348].

Claim 26 is drawn to a method of delivering a biologically active substance across a mucosal membrane, comprising introducing a nonparenteral multi-particulate formation comprising: a plurality of carrier particles; an oligonucleotide; and a penetration enhancer selected from the groups consisting of a fatty acid, bile salt, chelating agent and non-chelating non-surfactant, wherein said fatty acid is selected from the group consisting of oleic acid, lauric acid, capric acid, myristic acid, palmitic acid, stearic acid, linoleic acid, linolenic acid, dicaprate, tricaprate, moolein, diluarin, caprylic acid, arachidonic acid, glyceryl 1-monocaprate, 1-didecylazacycloheptan-2-one, acylcarnitines, acylcholines, monoglycerides, diglycerides, and salts thereof. Claim 27 is dependent on claim 26 and includes all the limitations of claim 26, with the further limitations, wherein said biologically active substance is an oligonucleotide and said formulation is administered orally.

Dean et al. disclose compositions and formulations for administration to an animal having enhanced bioavailability. The compounds of Dean et al. are encapsulated, conjugated, or otherwise associated with other molecules, molecule structures or mixtures of compounds, as for

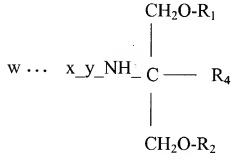
example, liposomes, receptor targeted molecules, oral, rectal, or other formulations for assisting in uptake, distribution, and/or absorption. The compositions and formulations for parenteral administration include sterile aqueous solutions which contain buffers, diluents, and other suitable additives such as, but not limited to, penetration enhancers, carrier compounds and other pharmaceutically acceptable carriers or excipients. Suitable pharmaceutically acceptable carriers useful in the formulations and compositions of Dean et al. include water, salt solutions, alcohol, polyethylene glycols, gelatin, polyacrylates, calcium sulfate, calcium hydrogen phosphate, lactose, amylose, magnesium sterate, talc, silicic acid, viscous paraffin, hydroxymethylcellulose, and polyvinylpyrrolidone (see page 19 and 22, for example). The compositions of Dean et al. comprise antisense oligonucleotides comprising at least one heteroatomic backbone modification. The compositions of Dean et al. having enhanced bioavailability further comprise a colloidal dispersion system, at least one penetration enhancer, wherein said penetration enhancer comprises a bile salt or fatty acid, wherein said bile acid is CDCA, and wherein said fatty acid is sodium caprate or sodium laureate. Various fatty acids and their derivatives which act as penetration enhancers may also include, for example, oleic acid, lauric acid, capric acid, myristic acid, palmitic acid, stearic acid, linoleic acid, linolenic acid, dicaprate, tricaprate, recinleate, monoolein, dilaurin, caprylic acid, arachidonic acid, and glycerol-1-monocaprate (see page 20).

Therefore, Dean et al. anticipate claims 26 and 27.

Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockett et al. [WO 97/25339].

Claims 26 and 27 are described above in the 102(a) rejection against claims 26 and 27 as being anticipated by Dean et al.

Lockett et al. disclose a method for introducing a nucleic acid into a cell comprising exposing the cell to a compound having the formula:



in which :

w is a nucleic acid, x is a non-amino acid or non-peptide nucleic acid binding group, y is a spacer having a chain length equivalent to 1-30 carbon-carbon single covalent bonds or is absent, R_4 is H or halogen or CH_2O-R_3; and R_1, R_2, and R_3 are the same or different and are either hydrogen, methyl, ethyl, alkyl, elkenyl, hydroxylated alkyl, hydroxylated alkenyl groups or ether containing alkyl, alkenyl, hydroxylated alkyl or hydroxylated alkenyl groups, optionally being an acyl group derived from a fatty acid having a carbon chain length equivalent to 3-24 carbon atoms saturated or unsaturated, with the proviso that at least one of R_1, R_2 or R_3 include a group having a carbon chain of 3-24 carbon atoms saturated or unsaturated; in which the R_1, R_2, and/or R_3 are cholesterol or acyl derivative of fatty acids selected from the group consisting of palmitate, myristate, laurate, caprate, and oleate; in which the method is conducted *in vivo*; in which the compound is administered orally or by suppository (see claims 1, 5, 10, and 11).

Therefore Lockett et al. anticipate claims 26 and 27.

Conclusions

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 746-8693.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
December 14, 2003

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER